DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Sonoscape Company Limited
% Mrs. Toki Wu
Regulatory Affairs Manager
Yizhe Building, Yuquan Road, Nanshan
Shenzhen Guandong 518051
P.R. CHINA

January 28, 2015

Re: K142815
Trade/Device Name: S22 Digital Color Doppler Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: August 29, 2014
Received: January 09, 2015

Dear Mrs. Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142815

Device Name
S22 Digital Color Doppler Ultrasound System

Indications for Use *(Describe)*
The SonoScape S22 system is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), Trans-esoph.(Cardiac), OB/Gyn and Urology.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

1. Submitter [21 CFR807.92 (a) (1)]

Submitter:	SonoScape Company Limited
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Date Prepared	August 29, 2014

2. Device [21 CFR807.92 (a)(2)]

Trade Name:	S22 Digital Color Doppler Ultrasound System
Common Name:	Diagnostic Ultrasound System and Transducers

Classification Regulatory:

	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

Classification Panel:	Radiology
Device Class:	II

3. Predicate Device(s) [21 CFR 807.92(a) (3)]

The identified predicate devices within this submission are as follows:

SonoScape S30 Digital Color Doppler Ultrasound System	K132527
Philips EPIQ Diagnostic Ultrasound System	K132304

4. Device Description [21 CFR 807.92(a) (4)]

This SonoScape S22 Digital Color Doppler Ultrasound System is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The basic principle is that system transmits ultrasonic energy into patient body and

implements post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body.

This system is a Track 3 device that employs a wide array of probes that include linear array, convex array and phased array with a frequency range of 2.0 MHz to 15.0 MHz.

This system consists of a mobile console with keyboard control panel, power supply module, color LCD monitor and optional probes.

This system is a mobile, general purpose, software controlled, color diagnostic ultrasound system. Its basic function is to acquire ultrasound data and to display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI, Color-Flow Doppler, Pulsed Wave Doppler, Continued Wave Doppler and Power Doppler, or the combination of these modes, Elastography, 3D/4D.

5. Intended Use [21 CFR 807.92(a)(5)]

The SonoScape S22 system is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), Trans-esoph.(Cardiac), OB/Gyn and Urology.

6. Comparison with the Predicate Devices [21 CFR 807.92(a) (6)]

S22 Digital Color Doppler Ultrasound System is comparable with and substantially equivalent to the predicate devices:

SonoScape S30 Digital Color Doppler Ultrasound System	K132527
Philips EPIQ Diagnostic Ultrasound System	K132304

Intended Use Comparison:

Compared with SonoScape S30 (K132527), the Subject Device S22 has the same intended uses.

Technical Characteristics Comparison:

The basic and main technical features of the subject device S22 are the same as the predicated device S30 (K132527), including Design, Operation Controls, Display Modes, Measurement Items, Cine Loop and Operating and Storage Condition.

For Operation Modes, Elastography is a special Operation Mode for the Subject Device S22, but already employed by many marketed devices and considered Substantially Equivalent to the Predicate Device Philips EPIQ (K132304) and detailed comparison analysis can be found in ***Substantial Equivalence Comparison***.

The detailed technical features comparison and analysis can be found in ***Substantial Equivalence Comparison*** and the detailed technical features can be found in ***General Device Descriptions*** of the submission.

Probes Comparison:

Subject device S22 has the similar probes as the predicated device SonoScape S30 (K132527).

Table 1 Probes Comparison

Subject device SonoScape S22	Predicate Device SonoScape S30	Remark
C322 Micro-curved Array C344 Curved Array C353 Curved Array C354 Curved Array C542 Curved Array	C322 Micro-curved Array C344 Curved Array C353 Curved Array C362 Curved Array C542 Curved Array	**SE** Analysis1
VC6-2 Curved Array	VC6-2 Curved Array	**Same**
C613 Micro-curved Array	C611 Micro-curved Array C311 Micro-curved Array	**SE** Analysis1
2P1 Phased Array 5P1 Phased Array	2P1 Phased Array 5P1 Phased Array	**Same**
L741 Linear Array L742 Linear Array L752 Linear Array 10L1 Linear Array	L741 Linear Array L742 Linear Array L743 Linear Array L752 Linear Array 10L1 Linear Array	**Same**
6V1 Micro-curved Array 6V3 Micro-curved Array EC9-5 Micro-curved Array BCC9-5 Micro-curved Array BCL10-5 Biplane (Micro-curved + Linear Array)	6V1 Micro-curved Array 6V3 Micro-curved Array EC9-5 Micro-curved Array BCC9-5 Micro-curved Array BCL10-5 Biplane (Micro-curved + Linear Array)	**Same**
MPTEE Phased Array (Multi-plane) MPTEE mini Phased Array (Multi-plane)	MPTEE Phased Array (Multi-plane) MPTEE mini Phased Array (Multi-plane)	**Same**

SE Analysis 1:

Compared with the predicate device, there are only two new probes (C354 and C613) for the subject device, but no new intended use. And the frequency and performance of C354 and C613 probes is the same as C353 and C611 respectively for predicate device.

Moreover, compared with predicated devices, the subject device (S22) complies with the same regulation and safety standards and has the consistent acoustic output levels. Therefore they can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.

7. Non-Clinical Tests [21 CFR 807.92(b) (1)]

The S22 Digital Color Doppler Ultrasound System has been evaluated for electrical, mechanical, thermal and electromagnetic compatibility safety, biocompatibility and acoustic output.

Laboratory tests were conducted to verify that the S22 system met all design specifications and the S22 system conformed to applicable medical device standards. Phantom test was conducted to verify that the strain Elastography function was effective and Elastography performance met design specifications, including accuracy and repeatability of strainratio measurement and etc.

The S22 system has been designed and manufactured to meet the following standards: IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37, ISO 10993-5, ISO10993-10, UD2, and UD3.

8. Clinical Test [21 CFR 807.92(b) (2)]

No clinical testing was required.

9. Substantially Equivalent Conclusions [21 CFR 807.92(b) (3)]

In accordance with the 21 CFR Part 807 and based on the information provided in this premarket notification, SonoScape Company Limited concludes that S22 Digital Color Doppler Ultrasound System is substantially equivalent to the predicate devices with regard to safety and effectiveness.